IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS AG, AND NOVARTIS PHARMA AG, Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC.., Defendants.	)	Civil Action No. 1:14-cv-111-IMK

MYLAN PHARMACEUTICALS INC.'S AND MYLAN INC.'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO STAY LITIGATION

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Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan") respectfully submit this brief in opposition to Plaintiffs' motion to stay this litigation.

I. INTRODUCTION

Despite the fact that all parties agree that the United States District Court for the Northern District of West Virginia is a proper forum to litigate this matter, Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, and Novartis Corporation (collectively, "Plaintiffs") yet again request this Court to stay this action as a "back up" in favor of proceeding in the United States District Court for the District of Delaware (D. Del., Civil Action No. 14-cv-00820-RGA, the "Delaware Action"). Like their previous request for a stay, this request should be denied.

Mylan's dispute over personal jurisdiction in the Delaware Action is far from over. Although the Delaware Court has denied Mylan Pharmaceuticals' motion to dismiss for lack of personal jurisdiction, the Federal Circuit has granted Mylan's Petitions for Interlocutory Appeal from other Delaware cases regarding issues of personal jurisdiction that are nearly identical to those at issue in the Delaware Action. *See Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, No. 14-935-LPS, 2015 U.S. Dist. LEXIS 4056, --- F. Supp. 3d ---- (D. Del. Jan. 14, 2015), *interlocutory appeal granted*, No. 2015-124, D.I. 21 (Fed. Cir. Mar. 17, 2015) ("*Acorda*"); *AstraZeneca AB v. Mylan Pharm., Inc.*, No. 14-696-GMS, 2014 U.S. Dist. LEXIS 156660, --- F. Supp. 3d ---- (D. Del. Nov. 5, 2014*), interlocutory appeal granted*, No. 2015-117, D.I. 31 (Fed. Cir. Mar. 17, 2015) ("*AstraZeneca*"). The Federal Circuit's decisions in *Acorda* and *AstraZeneca* will be dispositive of the personal jurisdiction issue in the Delaware Action. In the event the Federal Circuit finds that Mylan is not subject to personal jurisdiction in Delaware, the Delaware action will need to be dismissed, which will cause disruption that could have been

avoided by proceeding in the Northern District of West Virginia in the first place. To avoid such disruption of the parties' core patent dispute, Mylan has moved the Delaware Court to stay its proceedings while the personal jurisdiction issue is resolved by the Federal Circuit.

Judicial economy is best served by denying Plaintiffs' Motion and allowing the present action to proceed in this Court, as it would allow the parties to move forward without the uncertainty that would accompany proceeding in Delaware. Moreover, forward movement in this Court would not prejudice either party and would prevent needless disruption in resolving the underlying patent infringement disputes. The same cannot be said, however, if the opposite occurs and this case is stayed in favor of the Delaware Action.

Mylan, therefore, respectfully requests that this Court exercises its discretion and denies Plaintiffs' Motion to Dismiss, or in the alternative abstains from ruling on Plaintiffs' motion while Mylan's Motion to Stay is decided in the Delaware Action.

II. NATURE AND STAGE OF PROCEEDINGS

Plaintiffs have filed two patent infringement suits against Mylan each alleging that Mylan Pharmaceuticals' filing of ANDA No. 206585 for generic deferasirox (brand name EXJADE®) infringes two of Plaintiffs' patents. One suit was filed on June 25, 2014, the Delaware Action, and the other was filed one day later, on June 26, 2014, in the United States District Court for the Northern District of West Virginia (N.D.W.Va., Civil Action No. 14-cv-00111-IMK, the "West Virginia Action").

In the Delaware Action, on August 6, 2014, Mylan filed a Motion to Dismiss Plaintiffs' Complaint based on that District's lack of personal jurisdiction over both Mylan Inc. and Mylan Pharmaceuticals in place of filing an Answer. Delaware Action, D.I. 14. During the pendency of that motion, other judges in that District decided nearly identical issues of personal

jurisdiction involving Mylan defendants. *See, e.g., Acorda*, 2015 U.S. Dist. LEXIS 4056, (D. Del. Jan. 14, 2015), *interlocutory appeal granted*, No. 2015-124, D.I. 21 (Fed. Cir. Mar. 17, 2015); *AstraZeneca AB*, 2014 U.S. Dist. LEXIS 156660, (D. Del. Nov. 5, 2014), *interlocutory appeal granted*, No. 2015-117, D.I. 31 (Fed. Cir. Mar. 17, 2015). While, thus far, each opinion has held that Mylan Pharmaceuticals is subject to personal jurisdiction in Delaware, the legal bases for these determinations have been inconsistent. *See e.g., Acorda*, 2015 U.S. Dist. LEXIS 4056, at *44 ("Judge Sleet's rejection of consent as a basis for general jurisdiction over Mylan Pharma is well-reasoned and may well be the correct view. Nevertheless, for the reasons explained in this Opinion, the undersigned Judge has reached a different conclusion."). Mylan sought and received certification for interlocutory appeal of Chief Judge Stark's decision in *Acorda*, as well as Judge Sleet's decision in *AstraZeneca*. *See Acorda*, No. 14-935-LPS, D.I. 36 (D. Del. Jan. 30, 2015); *AstraZeneca AB v. Aurobindo Pharma Ltd.*, No. 14-664-GMS, 2014 U.S. Dist. LEXIS 180548 (D. Del. Dec. 17, 2014).

On March 16, 2015, the Delaware Court denied Mylan Pharmaceuticals' Motion to Dismiss and ordered jurisdictional discovery from Mylan Inc. Delaware Action, D.I. 57. With respect to general jurisdiction, the Delaware Court ultimately adopted the reasoning of the *Acorda* Court, finding that Mylan Pharmaceuticals (but not Mylan Inc.) is subject to general personal jurisdiction in Delaware because it complied with Delaware's registration statutes. Delaware Action, D.I. 56, at p. 5. The Delaware Court further indicated that "this is an important issue to get resolved in the Court of Appeals" and that "[b]randed companies are probably going to keep suing generic companies in districts in which the generic company is not 'at home.'" Delaware Action, D.I. 56, at p. 9.

The day after the Delaware Court issued its decision, the Federal Circuit accepted interlocutory review of the District of Delaware's personal jurisdiction decisions in *Acorda* and *AstraZeneca*. *Acorda*, 2015 U.S. Dist. LEXIS 4056, (D. Del. Jan. 14, 2015), *interlocutory appeal granted*, No. 2015-124, D.I. 21 (Fed. Cir. Mar. 17, 2015); *AstraZeneca AB*, 2014 U.S. Dist. LEXIS 156660, (D. Del. Nov. 5, 2014), *interlocutory appeal granted*, No. 2015-117, D.I. 31 (Fed. Cir. Mar. 17, 2015). Because the Delaware Court and all parties agree that "there are no substantive factual differences between [the Delaware Action] and *Acorda,*" the decision from the appellate court should be dispositive of the jurisdictional question in the Delaware Action. *See* Delaware Action, D.I. 56, at p. 6.[1]

After the Delaware Court's March 16, 2015 decision, in the Delaware Action, the parties filed a joint status report and a joint proposed scheduling order, Mylan filed its Answer, and the parties held a Rule 16 conference with the Delaware Court. All of which were done over the continued objection by Mylan to personal jurisdiction in Delaware. On March 31, 2015, Mylan filed a Motion to Stay the Delaware Action pending the Federal Circuit's decisions in *Acorda* and *AstraZeneca*. Delaware Action, D.I. 62.

[1]Mylan does not currently intend to certify the Delaware Court's personal jurisdiction decision for interlocutory appeal. Certification of the personal jurisdiction question in the Delaware Action may delay the briefing schedule in *Acorda* and *AstraZeneca* if the Federal Circuit were to consolidate a newly certified case with the pending ones. Moreover, as the Delaware Court indicated, "the Court of Appeals probably does not need multiple cases presenting the same issue," and because the Federal Circuit has now decided to review these issues, the need to signal the importance of these issues to the Federal Circuit has lessened. Regardless, certification is not required in order to preserve Mylan's objection to the Delaware Court's exercise of personal jurisdiction over it. *See* 16 Charles Alan Wright et al., Federal Practice & Procedure § 3920 (West 2014); *Rivera-Domenech v. Calvesbert Law Offices PSC*, 402 F.3d 246, 249 n.2 (1st Cir. 2005); *Colon v. R.K. Grace & Co.*, 358 F.3d 1, 4 (1st Cir. 2003); *Chi. Bd. of Educ. v. Substance, Inc.*, 354 F.3d 624, 626 (7th Cir. 2003) ("[I]t is almost never mandatory to file an interlocutory appeal in order to preserve an issue for appellate review.").

The West Virginia Action, unencumbered by the jurisdictional dispute, has been steadily proceeding. So far in the West Virginia Action: (i) the parties held a discovery planning meeting on February 12, 2015; (ii) Mylan served its first requests for production on February 12, 2015; (iii) the parties filed a joint status report on February 19, 2015; (iv) Novartis served its first set of interrogatories on February 23, 2015; (v) a scheduling conference was held on March 5, 2015 before this Court and a scheduling order was entered; (vi) parties filed their initial disclosures on March 12, 2015; (vii) the parties made their first production on March 16, 2015; (viii) Mylan served its responses and objections to the first set of interrogatories on March 23, 2015; (ix) Mylan made its second production on March 26, 2015; and (x) Mylan filed motions for clarification and to compel on March 30, 2015. All of these proceedings and discovery events are in stark contrast to the Delaware Action, which only recently held the Rule 16 conference and is generally lagging behind the West Virginia Action..

III. ARGUMENT

In seeking a stay, Plaintiffs "must justify it by clear and convincing circumstances outweighing potential harm to the [non-moving] party" and "make out a clear case of hardship or inequity in being required to go forward." *Williford v. Armstrong World Indus., Inc.*, 715 F.2d 124, 127 (4th Cir. 1983) (quoting *Landis v. N Am. Co.,* 299 U.S. 248, 254-55 (1936)). Plaintiffs' burden here is particularly high, given that this is a Hatch-Waxman action, for which Congress has legislated a statutory timetable to "bring cheaper, generic copies of [] drugs to market." *See Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000); *see also In re Brimonidine Patent Litig.*, No. 07-md-1866 GMS, 2008 WL 4809037 (D. Del. Nov. 3, 2008) (denying plaintiff pharmaceutical company's motion to stay because the stay would most likely delay market entry of the generic product).

"The grant or denial of a request to stay proceedings calls for an exercise of the district court's judgment 'to balance the various factors relevant to the expeditious and comprehensive disposition of the causes of action on the court's docket.'" *Md. v. Universal Elections, Inc.*, 729 F.3d 370, 375 (4th Cir. 2013) (quoting *U.S. v. Ga. Pac. Corp.*, 562 F.2d 294, 296 (4th Cir. 1977)).

For the reasons set forth below, Plaintiffs have not met their high burden that a stay of the present action is warranted.

A. This Court Should Deny Plaintiffs' Motion Because Personal Jurisdiction Remains A Contested Issue in Delaware

In determining whether to stay a second-filed action, courts consider various factors such as the "absence of jurisdiction over all necessary or desirable parties" in the first-filed action. *See Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1348 (Fed. Cir. 2005). This is because "[t]he first-to-file rule is an equitable doctrine traditionally standing for the proposition that '[i]n all cases of concurrent jurisdiction, the Court which first has possession of the subject must decide it.'" *Pfizer, Inc. v. Mylan, Inc.*, No. 1:09-CV-79, 2009 U.S. Dist. LEXIS 124954, at *4 (N.D. W. Va. Nov. 20, 2009). "Importantly, in first-filed cases where jurisdiction is unsettled, courts have held that the first-to-file rule does not apply." West Virginia Action, D.I. 38, p. 8 (citing *Genentech, Inc. v. Eli Lilly and Co.*, 998 F.2d 931, 938 (Fed. Cir. 1993) and *Orthmann v. Apple River Campground, Inc.,* 765 F.2d 119, 121 (8th Cir. 1985)).

The decision in *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484 (E.D. Va. 2005) is instructive. In *Aventis*, plaintiffs filed a first complaint against defendants in the District of Maryland and an identical suit later in the Eastern District of Virginia as a protective measure. *Id.* at 488. Defendants consented to jurisdiction in the Eastern District of Virginia and moved to dismiss the Maryland case for lack of personal jurisdiction. *Id.* at 488,

490. Like Plaintiffs here, the plaintiffs in *Aventis* relied on the first-to-file rule to justify a stay of the Virginia case. In denying plaintiffs' motion to stay, the Virginia district court gave great weight to the fact that there was a pending jurisdictional dispute in the first-filed case. *Id.* at 490 ("If the Maryland forum is in any way questionable in order to necessitate a 'protective filing' as Plaintiffs maintain, then this Court is clearly the better forum, as all of the parties agree that both jurisdiction and venue lie here.") (emphasis in original). Accordingly, where, as here, there remains a question of jurisdiction in the first-filed forum, the second-filed forum should exercise its discretion and deny the motion to stay.

Importantly, the resolution of the jurisdictional dispute in Delaware is not likely to be resolved for many months; a fact that is not changed by Judge Andrews' recent opinion in the Delaware Action. Although Judge Andrews found jurisdiction over Mylan Pharmaceuticals, he recognized that "this is an important issue to get resolved in the Court of Appeals." *Novartis Pharm. Corp. v. Mylan Inc.*, No. 14-820-RGA, 2015 U.S. Dist. LEXIS 31812, at *13-14 (D. Del. Mar. 16, 2015). Other Delaware Courts have similarly determined that personal jurisdiction for Hatch-Waxman cases is unsettled. *See Aurobindo Pharma Ltd.*, 2014 U.S. Dist. LEXIS 180548, at *4-5 n.1 ("this is a controlling [and novel] question of law as to which there is substantial ground for difference of opinion . . . . [T]he court is of the view that interlocutory appellate review will provide necessary guidance as to whether [ANDA] cases are properly before the court."); *Acorda*, 2015 U.S. Dist. LEXIS 4056, at *44 n.20 ("The undersigned Judge wholeheartedly agrees with Judge Sleet that the existence of personal jurisdiction in an ANDA case in a post-*Daimler* world is an important question of first impression that will be (and has been) raised in many ANDA cases.") (internal citation omitted).

Accordingly, the jurisdictional issue remains heavily disputed in Delaware and will not be resolved until the Federal Circuit issues its decisions in *Acorda* and *AstraZeneca*. Therefore, the Court should deny Plaintiffs' Motion and allow this case to proceed in the Northern District of West Virginia.

B. This Court Should Exercise Its Discretion to Deny Staying the Present Action

This Court has sound discretion in granting or denying a motion to stay. *W. Va. Highlands Conservancy v. Monongahela Power Co.*, No. 1:11cv71, 2012 WL 11122, at *5 (N.D. W. Va., Jan. 3, 2012). Factors for this Court to consider include "(1) the interests of judicial economy; (2) hardship and equity to the moving party if the action is not stayed; and (3) potential prejudice to the non-moving party.'" West Virginia Action, Order Denying Plaintiffs' Motion to Stay Pending Resolution of Jurisdictional Challenge to First-Filed Delaware Case, D.I. 38, p. 10 (citing *Tolley v. Monsanto Co.*, 591 F.Supp.2d 837, 844 (S.D. W. Va. 2008)) (internal citation omitted).

Judicial economy would be best served by allowing this case to move forward in this Court. While the jurisdictional issue works its way to resolution in the appellate courts, Mylan is ready to proceed with this litigation here—the only Court with which there is no dispute as to jurisdiction. However, there is a real and substantial risk of wasting judicial resources if this stay is granted and the parties' dispute proceeds in Delaware. Under that scenario, if the Federal Circuit reverses the *Acorda* decision, determining that Delaware lacks personal jurisdiction over Mylan Pharmaceuticals, the Delaware Court would be compelled to follow the Federal Circuit's determination and dismiss the Delaware Action for lack of personal jurisdiction over Mylan Pharmaceuticals. *See Sonera Holding B.V. v. Cukurova Holding A.S.*, 750 F.3d 221, 227 (2d Cir. 2014) (reversing the district court's judgment denying defendant's motion to dismiss for lack of

personal jurisdiction, vacating the subsequent judgments of the district court, remanding the case to the district court, and directing the court to dismiss the action for lack of personal jurisdiction). Any progress made in litigating the case in Delaware, therefore, would be wasted. *See Stadler v. McCulloch*, 882 F. Supp. 1524, 1527-28 (E.D. Pa. 1995) (granting a motion to stay to "await the Third Circuit's decision and proceed accordingly, rather than charging forward, possibly to trial, knowing that [a District Court] may be compelled to return to this point and begin anew."). Further, any substantive rulings made on the issues by the Delaware Court would be vacated. *See id.*

By contrast, substantive rulings by this Court would ***not*** have the same risk of being vacated. All parties agree that the Northern District of West Virginia is has jurisdiction to resolve the underlying Hatch-Waxman dispute. Thus, decisions made by this Court do not have the shadow of uncertainty looming over them. Accordingly, unlike the Delaware Action, any decisions made by these Court could be maintained or transferred; and thus, the risk for judicial waste is not present here.

As to the second factor, "hardship and equity" to Plaintiffs if this action is not stayed, this Court has already noted that there would be none: "Novartis will not suffer hardship or inequity by litigating here. It filed suit in this Court as a protective measure, and cannot fairly complain because the suit is progressing here now." West Virginia Action, D.I. 38, p. 14.

On the other hand, granting a stay would prejudice Mylan. A stay here in favor of the Delaware Action would be unfairly prejudicial and would inflict irreparable injury on Mylan's due process rights by forcing Mylan to litigate in a court where jurisdiction is unsettled. *See Painewebber Inc. v. Chase Manhattan Private Bank (Switz.)*, 260 F.3d 453, 461 (5th Cir. 2001) (indicating that Chase-Switzerland made a credible claim that "an improper exercise of personal

jurisdiction ... constitutes irreparable injury as a matter of law [as a violation of due process]"); *Avocent Huntsville Corp. v. Aten Int'l Co., Ltd.*, 552 F.3d 1324, 1329-30 (Fed. Cir. 2008) (indicating that an improper finding of personal jurisdiction violates a defendant's constitutional due process rights).

In view of the foregoing, the Court should grant Mylan's motion to stay.

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully requests the Court to deny Plaintiffs' Motion or, in the alternative, abstains from ruling on Plaintiffs' motion while Mylan's Motion to Stay is decided in the Delaware Action in order to avoid delaying the resolution of the parties' core patent dispute.

Respectfully submitted this 9th day of April, 2015.

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CERTIFICATE OF SERVICE

I, hereby certify that on 9th day of April, 2015, the foregoing "Mylan Pharmaceuticals Inc.'s and Mylan Inc.'s brief in opposition to Plaintiffs' motion to stay litigation following resolution of Defendants' personal jurisdiction challenge in Delaware" was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification to the following registered attorneys of record that the document has been filed and is available for viewing and downloading.

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